AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A solid pharmaceutical composition comprising tacrolimus containing particles, wherein the particles comprise (i) tacrolimus in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer, ~~wherein the tacrolimus, polyethylene glycol and poloxamer are on~~ and (ii) a solid carrier, wherein the tacrolimus is present ~~therein~~ in the composition at a concentration of between 0.01 w/w% and 15 w/w%~~, wherein the solid pharmaceutical is in particulate form~~.

2. (Canceled)

3. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the tacrolimus is partly dissolved in the polyethylene glycol and the poloxamer to form a mixture of solid dispersion and solid solution at ambient temperature.

4. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the tacrolimus is fully dissolved in the polyethylene glycol and the poloxamer to form a solid solution at ambient temperature.

5. (Currently Amended) The solid pharmaceutical composition according to claim 1, wherein the polyethylene glycol and the poloxamer ~~has~~ have a melting point of at least 30 °C.

6. (Currently Amended) The solid pharmaceutical composition according to claim 1, wherein the concentration of tacrolimus in the ~~vehicle~~ polyethylene glycol and poloxamer is at the most 10w/w%.

7. (Currently Amended) The solid pharmaceutical composition according to claim 1, wherein the concentration of tacrolimus in the ~~vehicle~~ polyethylene glycol and poloxamer is at least 0.05w/w%.

8. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein at least 50 w/w% of the tacrolimus is released within 30 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

9. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein at least 75 w/w% of the tacrolimus is released within 40 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

10. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein at least 90 w/w% of the tacrolimus is released within 60 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

11-15. (Canceled)

16. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the mixture comprises a polyethylene glycol and a poloxamer in a proportion of between 1:3 and 10:1.

17. (Previously Presented) The solid pharmaceutical composition according to claim 16, wherein the poloxamer is poloxamer 188.

18. (Previously Presented) The solid pharmaceutical composition according to claim 16, wherein the polyethylene glycol has an average molecular weight of about 6000 (PEG6000).

19. (Previously Presented) The solid pharmaceutical composition according to claim 1, comprising one or more pharmaceutically acceptable excipients.

20. (Previously Presented) The solid pharmaceutical composition according to claim 19, wherein the pharmaceutically acceptable excipients are selected from the group consisting of fillers, disintegrants, binders and lubricants.

21. (Canceled)

22. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the particles have a geometric weight mean diameter d_{gw} from 10 μm to 2000 μm.

23. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the particles have a geometric weight mean diameter d_{gw} from 50 μm to 300 μm.

24. (Previously Presented) A solid dosage form comprising the solid pharmaceutical composition according to claim 19, which is a solid oral dosage form.

25. (Previously Presented) The solid dosage form according to claim 24, which is a unit dosage form.

26. (Previously Presented) The solid dosage form according to claim 24, which further comprises a pharmaceutically acceptable additive selected from the group consisting of flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and release modifying agents.

27. (Previously Presented) The solid dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is selected from the group consisting of silica acid or salt thereof.

28. (Previously Presented) The solid dosage form according to claim 24, wherein at least one pharmaceutically acceptable excipient is a silica acid or salt thereof.

29. (Previously Presented) The solid dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is silicon dioxide or a polymer thereof.

30. (Canceled)

31. (Previously Presented) The solid dosage form according to claim 26 comprising one or more release modifying agents selected from the group consisting of water-miscible polymers, water-insoluble polymers, oils and oily materials.

32. (Previously Presented) The solid dosage form according to claim 31, wherein the water-insoluble polymer is selected from the group consisting of ethyl cellulose, cellulose acetate, cellulose nitrate, and mixtures thereof.

33. (Previously Presented) The solid dosage form according to claim 31, wherein the oil or oily material is selected from the group consisting of hydrophilic and hydrophobic oils or oily materials.

34. (Previously Presented) The solid dosage form according to claim 31, wherein the oil or oily material is hydrophilic and selected from the group consisting of polyether glycols and mixtures thereof.

35. (Canceled)

36. (Currently Amended) The solid dosage form according to claim 31, wherein the oil or oily material is hydrophobic and selected from the group consisting of straight chain saturated hydrocarbons, sorbitan esters, paraffins; fats and oils; higher fatty acid, stearic acid, myristic acid, palmitic acid, higher alcohols, low melting point waxes, ~~substituted and/or unsubstituted diglycerides, substituted and/or unsubstituted triglycerides,~~ yellow beeswax, white beeswax, carnauba wax, castor wax, japan wax, acetate monoglycerides; NVP polymers, PVP polymers, acrylic polymers, and mixtures thereof.

37. (Previously Presented) The solid dosage form according to claim 36, wherein the oil or oily hydrophobic material has a melting point of at least 20 °C.

38. (Previously Presented) The solid dosage form according to claim 31, wherein the water-miscible polymer is a cellulose derivative selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, poloxamers, polyoxyethylene stearates, poly-s-caprolactone, polyvinylpyrrolidone (PVP), polyvinylpyrrolidone-polyvinylacetate copolymer PVP-PVA, polymethacrylic polymers and polyvinyl alcohol (PVA), poly (ethylene oxide) (PEO) and mixtures thereof.

39. (Previously Presented) The solid dosage form according to claim 38, wherein the polymethacrylic polymers are selected among Eudragit® RS, Eudragit® RL, Eudragit® NE and Eudragit® E.

40. (Previously Presented) The solid dosage form according to claim 31, which is entero-coated using a water-miscible polymer having a pH-dependant solubility in water.

41. (Previously Presented) The solid dosage form according to claim 40, wherein the water-miscible polymer is selected from the group consisting of polyacrylamides; cellulose acetate phthalate, cellulose acetate terephtahalate, cellulose acetate isophthalate, cellulose ester phthalates, cellulose ether phthalates, hydroxypropyl cellulose phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropyl ethylcellulose phthalate, hydroxypropyl methylcellulose phthalate (HMPCP), methylcellulose phthalate, methyl cellulose acetate phthalate, polyvinyl acetate phthalate, polyvinyl acetate hydrogen phthalate, sodium cellulose acetate phthalate, starch acid phthalate; polyvinyl acetate phthalate (PVAP); hydroxypropyl methylcellulose acetate succinate (HPMCAS), carboxymethylcellulose, cellulose acetate trimellitate; alginates; carbomers; polyacrylic acid derivatives, polymethacrylic acid and esters thereof, poly acrylic methacrylic acid copolymers, methacrylic acid copolymers, styrene-maleic acid dibutyl phthalate copolymer, styrene-maleic acid polyvinylacetate phthalate copolymer, styrene and maleic acid copolymers; shellac, starch glycolat; polacrylin; vinyl acetate and crotonic acid copolymers and mixtures thereof.

42. (Previously Presented) The solid dosage form according to claim 40, which upon oral administration to a mammal in need thereof releases at the most about 10% w/w of the tacrolimus within the first 3 hours following administration.

43. (Previously Presented) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof provides an AUC or C_{max} of tacrolimus that is 80%-125% of that provided by a capsule dosage form approved under U.S. Food and Drug Administration NDA No. 050708, wherein the dose of tacrolimus administered with the solid dosage form is at the most about 85% w/w of the dose of tacrolimus administered in the form of the capsule dosage form approved under NDA No. 050708.

44. (Currently Amended) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof releases at least 50% w/w of the tacrolimus ~~active ingredient~~ within 24 hours.

45-50. (Canceled)

51. (Previously Presented) A method for the preparation of the solid pharmaceutical composition according to claim 1, the method comprising the steps of (a) dispersing and/or dissolving tacrolimus in a polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer to form a mixture, and (b) spraying the mixture onto a solid carrier to obtain the solid pharmaceutical composition.

52. (Previously Presented) The method according to claim 51, wherein step (a) is performed in the absence of an organic solvent.

53. (Previously Presented) A solid pharmaceutical composition prepared according to the method of claim 51.

54. (Previously Presented) A solid pharmaceutical composition prepared according to the method of claim 52.

55. (Previously Presented) The solid pharmaceutical composition according to claim 1, wherein the solid pharmaceutical composition is a tablet.

56. (Previously Presented) A solid pharmaceutical composition comprising tacrolimus dispersed or dissolved, in the absence of an organic solvent, in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer, wherein the tacrolimus is present therein in a concentration of between about 0.01 w/w% and about 15 w/w%, wherein the solid pharmaceutical is in particulate form.

57. (Previously Presented) The solid dosage form according to claim 31, wherein the release modifying agent is hydroxypropyl methylcellulose (HPMC).

58. (New) A solid pharmaceutical composition comprising agglomerated particles comprising a solid carrier and tacrolimus dispersed or dissolved in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer, wherein

(i) the tacrolimus is present in the composition at a concentration of between about 0.01 w/w% and about 15 w/w%,

(ii) the particles have a geometric weight mean diameter d_{gw} of from 100 to 1000 μm, and

(iii) the weight ratio of polyethylene glycol to poloxamer is between 1:3 and 10:1.

59. (New) A solid pharmaceutical composition prepared by

(a) spraying a solid carrier with tacrolimus dispersed or dissolved in polyethylene glycol having an average molecular weight of 1500 to 8000 and a poloxamer,

(b) mechanically working the product from step (a) to form agglomerated particles having a geometric weight mean diameter d_{gw} of from 100 to 1000 μm, and

(c) compressing the agglomerated particles,

wherein

(i) the tacrolimus is present in the composition at a concentration of between about 0.01 w/w% and about 15 w/w%, and

(ii) the weight ratio of polyethylene glycol to poloxamer is between 1:3 and 10:1.

60. (New) The solid pharmaceutical composition according to claim 59, wherein step (c) comprises compressing the agglomerated particles into a tablet.